

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE:) 19-MD-2875(RBK-JS)
)
) Camden, NJ
VALSARTAN NDMA PRODUCTS) September 12, 2019
LIABILITY LITIGATION) 4:03 p.m.

TRANSCRIPT OF TELEPHONIC STATUS CONFERENCE
BEFORE THE HONORABLE JOEL SCHNEIDER
UNITED STATES MAGISTRATE JUDGE

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Colloquy

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1 (The following was heard via telephone conference at
2 4:05 p.m.)

3 THE COURT: Good afternoon, counsel. This is Judge
4 Schneider. We're on the record, In the Valsartan MDL Docket
5 No. 19-2875.

6 If you want to enter your appearance, let's put your
7 names on the record, starting with plaintiffs.

8 MR. NIGH: Good afternoon, Your Honor. This is
9 Daniel Nigh for the plaintiffs.

10 THE COURT: Anyone else on the line for the
11 plaintiffs? Let's go. Okay, Mr. Nigh, you're flying solo
12 today?

13 MR. NIGH: I thought that there were others on line,
14 wonder if they have (inaudible), that they're un-muting their
15 lines.

16 MR. SLATER: We're sorry, Your Honor. Adam Slater
17 for the plaintiffs as well.

18 MS. WHITELEY: And Conlee Whiteley.

19 THE COURT: All right. Defendants.

20 MR. GOLDBERG: This is Seth Goldberg for the CHP
21 parties, and the joint defense group.

22 MS. LOCKARD: Good afternoon, Your Honor, Victoria
23 Lockard from Greenberg Traurig for the TEVA defendants.

24 MR. REEFER: Good afternoon, Your Honor. Jason
25 Reefer from the Pietragallo firm filling in for Clem Trischler

1 on behalf of Mylan Pharmaceuticals.

2 THE COURT: Okay. That's it. All right. I have
3 your letters. And thank you, Ms. Lockard, your office was
4 kind enough to send me a copy of the fact sheet, the latest
5 version of it, which is very, very helpful to understanding
6 the issues.

7 Before we get into the issues in your letters, I
8 would like to just get the lay of the land a little bit with a
9 couple of background questions. With regard to the service on
10 the Hague, any update on that, pursuant to the Hague?

11 MR. SLATER: Nothing new, Your Honor, as far as we
12 know since meeting.

13 THE COURT: CMO-12 required plaintiffs to serve
14 their document requests by August 30, was that done?

15 MR. SLATER: The document requests were served. I
16 can't remember if we agreed to a short extension of those
17 dates, but they were served and defense have those.

18 THE COURT: Terrific. By September 6, plaintiffs
19 were to serve their 30(b)(6) notices if they were going to
20 take those depositions on Ketero and Aurobindo. Was that
21 done?

22 MR. SLATER: Yes. And, Your Honor, to clarify --
23 again, it's is Adam Slater -- that was the -- we agreed to a
24 short extension with the defense on that. We can give you the
25 dates if you need it, Your Honor. There's a couple of dates

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1 on each end, and we can submit that to the Court if necessary
2 so that you have it. But that was served.

3 THE COURT: No, I don't need that. Presently,
4 objections are due by September 20. And if there are any
5 objections that you can't work out, would you please bring
6 them to my attention, because those depositions are to be
7 completed by October 31, with motions due by November 15,
8 okay?

9 Got that, counsel?

10 MR. SLATER: Yes, Your Honor.

11 THE COURT: In a few days the September 16, the
12 first draft of the search terms and custodians are due. Is
13 that on track?

14 MR. SLATER: For plaintiffs, yes, Your Honor.

15 MR. GOLDBERG: Your Honor, this is Seth Goldberg for
16 defendants. We were actually going to reach out to plaintiffs
17 today to see if we could get an extra week on our custodians.
18 And we would in turn give plaintiffs an extra week on the ESI
19 search terms.

20 MR. SLATER: We certainly wouldn't object if they
21 need another week. I would expect that we're going to still
22 be on track to serve our search terms by the close of business
23 Monday. But I appreciate their offer, and if we have the
24 supplement maybe for the next week we could, but we think
25 we're on track for -- for Monday.

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1 THE COURT: Mr. Goldberg, that's okay with the
2 Court. But let's work backwards a little bit. We have a
3 December 11 deadline -- we have a December 11 deadline to
4 address all document and ESI disputes. That deadline will not
5 be changed. We pushed it back to December to give the parties
6 all sorts of time to tee up that issue. That may be the most
7 important, or one of the most important substantive issues we
8 have to deal with to get this case going, what documents are
9 going to be produced and what ESI are going to be produced.

10 So I don't have any problem if you and the
11 plaintiffs agree to push back by a week the exchange of search
12 terms and custodians. The present deadline to serve the
13 defendant's objections is October 15. We're not changing that
14 deadline, so you have plenty of notice where we're going in
15 the case.

16 So you're on notice of the Court's position. Okay?

17 MR. GOLDBERG: Thank you, Your Honor.

18 MR. SLATER: And could I suggest something maybe to
19 Mr. Goldberg through Your Honor? Because of what you just
20 said, you know, maybe it would make sense to serve their list
21 -- your list as of Monday, and then, you know, obviously we
22 object if you supplement for the next seven days, but at least
23 we would -- we would have a good idea of what's there, so we
24 can get to work on that and get started.

25 Is that something that is possible? Because

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1 obviously we can start processing and delve into this.

2 MR. GOLDBERG: No. I think -- I think that's why we
3 need the extra week, we're not ready, we'll provide them to
4 you on Monday, so we will -- and we will certainly endeavor to
5 have a meet and confer as quickly as we can after do. But we
6 would like to, you know, have that week -- that extra week
7 just to provide that.

8 MR. SLATER: We'll still endeavor to serve our
9 search terms by close of business Monday, just to keep things
10 moving quickly.

11 THE COURT: All right. We're going to -- we're
12 going to stay on top of you on this issue, because it's
13 critical to getting the case moving.

14 Okay. Let's go to the issues on the agenda. And I
15 have no problem proceeding in the order that you suggested.
16 Let me just get out my letter. I think the first issue is the
17 fact sheets. And the first issue on the fact sheets has to do
18 with the lot numbers, right -- lot and batch numbers?

19 MR. SLATER: We agreed to that. I don't want to make
20 -- I don't want to -- I don't want to waste your time. We
21 emailed defense counsel several hours ago and told them we're
22 agreed that in to the extent it may be known based on the
23 information the plaintiff has.

24 THE COURT: Okay.

25 MR. SLATER: So we have no objection to the lot

1 number and batch number if known.

2 THE COURT: Thank you, Mr. Slater. I would put that
3 in the no brainer category. It's clearly relevant, and I -- I
4 have to add this, because I just noticed it when I reviewed
5 this draft this morning, on page two on the bottom of the fact
6 sheet, as I read it, it requires the production of
7 prescription and pharmacy records, right? And photographs of
8 prescription bottles or labels in your possession.

9 So isn't that where the lot or batch number would
10 be?

11 MR. SLATER: If it exists, that's where it would be.
12 I think that falls under the category of no brainer.

13 (Laughter)

14 MS. LOCKARD: Well, if they are there, Judge, -- if
15 I may, this is Victoria Lockard for the record. There is some
16 discrepancy, so you would hope that that would be there, but
17 what we understand is that that is not always the case.

18 And in many instances it's not in the record. And
19 even according to Ms. (sic) Goldberg at our meet and confer
20 said that she has so many samples where -- and it wasn't in
21 those records. So, you know, I do think that both parties
22 need to take, you know, responsibility for drumming this up,
23 but if it's available to plaintiffs, if it's on -- readily
24 available on the label, then they can provide it and, you
25 know, defendants will do their part as well.

Colloquy

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1 But I think we've worked this out.

2 THE COURT: Okay. And if it's on the recall letter,
3 you know, put it there too. But it's clearly relevant and
4 clearly has to be provided. So I think we have a meeting of
5 the minds on that.

6 MR. SLATER: Thank you, Your Honor. If I could just
7 inform the Court of something that came up, and I think it's
8 an important issue, and I'm hoping to resolve it. But if not,
9 I think it's important Your Honor's aware of this.

10 In the context -- this specific issue, we requested
11 of the defense a methodology to figure out all the lots and
12 batches from all the defendants that are contaminated, and a
13 methodology to cross-reference to whatever information the
14 plaintiffs have, whether it's the lot and batch numbers that
15 may be disclosed, if so, or NBC Code or whatever it is,
16 because ultimately what we're all going to need in this
17 litigation is a Rosetta Stone that we can all go to to know
18 which pills were contaminated and which were not.

19 And that could be a very critical foundational fact,
20 and we raised that with the defense, they're looking into it.
21 But from our perspective, that's going to be something that we
22 really need to push hard on to get that done as fast as we
23 can, hopefully this year.

24 THE COURT: It sounds very logical to me, Mr.
25 Slater. I do recall seeing, I can't put my finger on the

1 particular website now, it may be the FDA website where there
2 is a compilation of all the lot and batch numbers that have
3 been recalled. Frankly, I don't know if those include
4 voluntary recalls. But, you know, I remember seeing that list
5 it was lots of pages, months ago. I assume it's still there,
6 so maybe that could be a start for what you're looking for.

7 I don't know exactly what you're looking for, but I
8 think it is relatively easy to retrieve, at least the FDA
9 recall lot and batch numbers. And, again, I don't know if
10 that includes the voluntary recalls.

11 MR. SLATER: Exactly, Your Honor. And our interest
12 is, obviously, as Your Honor stated, any recall batches or
13 lots, however they term those, and also to identify all lots
14 and batches that were contaminated, which would include pills
15 that were never recall because they were sold and consumed
16 over the -- the last four years or five years, or however long
17 it's been.

18 THE COURT: Okay. I agree it's an important issue,
19 Mr. Slater, and if necessary just keep the Court involved, and
20 we'll do what is necessary to move that process along.

21 MR. SLATER: Thank you. Will do.

22 THE COURT: Let me go by the order in defendant's
23 letter. The second issue they have is the list of medical
24 conditions. And this goes to the eight or nine disputed
25 conditions on the draft fact sheet. I have this question for

1 the defendants. Can you help the Court understand how this
2 list was derived? What I'm specifically interested in is, did
3 you go to an expert or consultant and say, these are the
4 things we need to determine -- what do we need to determine if
5 the alleged cancer was caused by these drugs? And they gave
6 you these conditions.

7 Or is this just a list that the lawyers came up with
8 that they think would be helpful for discovery purposes?

9 MS. LOCKARD: It is most certainly the former, Your
10 Honor. And it includes items that are either symptoms, or
11 markers, or risk factors. And I have before me, which I'm
12 happy, you know, to go through. But we have a source for
13 every one of these that is on this narrowed list. You know,
14 I'll be quite candid, there were probably some on this list at
15 the outset when we had 84, or eighty something that didn't
16 need to be there, that got just put in in the process.

17 We were making efforts to winnow these down. We
18 exhausted -- or, you know, we eliminated 30 or more. We're
19 now down to a number that -- in the fifties, well below the
20 seventy that were allowed in Benicar, on Benicar's fact sheet.

21 And, you know, I can tell you just, you know, for
22 example, you know, if you look at the National Cancer
23 Institute's database for providers and patients that summarize
24 the signs information of all cancer, you'll find that -- you
25 know, constipation, diarrhea. And though they're generalized,

1 I realize they convened on specific, but we think things like
2 that are important in this case, and we've included the
3 modifier in our negotiations, instead of just, have you been
4 treated for constipation, but persistent constipation. And
5 keep in mind this is not just things that somebody's been --
6 you know, someone has experienced in their lifetime, it has to
7 be something they've actually been treated for.

8 If you've been treated for persistent constipation,
9 that's a symptom of colon cancer, and we think we're entitled
10 to ask about it. You know, certainly in something that's as
11 easy as a yes or no check the box, which we all do, you know,
12 when we go see our treating physician anyway.

13 And I'm happy to run down the list in alphabetical
14 order and give you a presentation, because here are these
15 studies, the National Cancer Institute. But I assure you I
16 can do it for every one of these.

17 THE COURT: I accept your representation. Does
18 anyone want to speak to this for the plaintiffs?

19 MR. SLATER: Yes, Your Honor. I'm looking at the
20 form, I'm looking at the bottom of page 22 on the red line
21 that Ms. Lockard circulated prior to the call. It says have
22 you been diagnosed or treated for any of the conditions in the
23 past ten years. So if counsel is, as a foundational step
24 wants to limit this to what people have been treated for, then
25 the diagnosed part should probably be removed.

1 And if we were to go through these items it may be
2 constipation is a -- I'll give the example counsel gave,
3 persistent constipation is a potential marker for colon
4 cancer, I'll leave it to the Court. But our feeling was that
5 constipation, I mean, I guess diarrhea and nausea, vomiting I
6 suppose those could be markers of all sorts of things. We
7 just felt that just looking at those examples right now before
8 we go through the list, that they're very, very generic.

9 If you go through the entire list, for example,
10 diagnosed and treated depression, anxiety, that obviously has
11 nothing to do with cancer, and it's addressed already on the
12 questions about depression and anxiety. So it really
13 shouldn't be here. Diverticulitis, it's -- that's a -- that's
14 an isolated intestinal condition. I suppose somebody with
15 that could ultimately develop cancer also, but -- and she goes
16 down this list, intestinal obstruction, et cetera, these very
17 generic.

18 Now if they want to limit it to just somebody being
19 treated for these conditions, then obviously we would shorten
20 this, but there is a burden here. Because if you look at the
21 next -- and I'm obviously not going through every one on the
22 list for time purposes.

23 But if you go to Section G on page 24, it's not just
24 simply you have to list these conditions, you also have to
25 then list everybody that treated you for it, when is the date

1 of onset, when the treatment took place, et cetera. So you
2 then have to have to provide that information, and then
3 presumably the defense is going to want to obtain all the
4 records. And there's going to be authorizations, and there's
5 going to be costs.

6 So our interest was we think that notice was massive
7 when it started, we think it's still too long, and we think
8 that the generic conditions that are here -- and, frankly,
9 conditions that did come directly off the Benicar list, what
10 the factory filled (inaudible). And I think we had
11 unexplained weight loss. These are so generic, and -- and
12 really so far out there, that we really felt like it should be
13 more appropriate.

14 With an understanding of what the Court told us
15 during the last conference, you truly wanted to limit this to
16 things that would be more significant. Because, again, they
17 are going to have the medical records for thee plaintiffs, as
18 Your Honor has already ordered, from the primary doctor, the
19 primary care people, and anybody that diagnosed or treated
20 their cancer.

21 THE COURT: Can I ask you a question, Mr. Slater?
22 When a -- when a plaintiff has to fill out these forms, and we
23 know that subsection (f) is a yes or no, that's pretty simple.
24 But when we get to the information requested regarding the
25 conditions in (g), do the plaintiffs envision that it will be

1 sufficient to just refer to the identified treater's medical
2 records?

3 Or do they envision they're going to have to go to
4 the records and actually write down every date of treatment,
5 diagnosis, visit, et cetera?

6 MR. SLATER: That's a loaded question. Plaintiffs
7 would prefer the refer to the record, but my experience with
8 this Court is that there would be an expectation that if the
9 question asks for dates, but the plaintiff will have to do
10 their best to give dates and names, et cetera. I mean, my
11 understanding from Your Honor's manner of handling this
12 throughout this MD -- throughout the Benicar litigation was
13 that they would be obligated to do their best to provide the
14 information.

15 That would be my expectation.

16 THE COURT: What's your expectation, defendant?

17 MS. LOCKARD: Well on that particular question, we
18 -- we asked when we requested records we have to identify the
19 dates of treatment. And we do have to know who the provider
20 is, that information at least, and dates of treatment, that --
21 that information is important.

22 But if you have the physician where he or she said,
23 you know for a particular issue, we don't expect plaintiff to
24 just list every (inaudible) doctor, I think theory is -- and
25 this is consistently (inaudible) it's, you know --

1 THE COURT: Counsel, you're breaking -- counsel,
2 you're breaking up a little bit. I don't know if you're on a
3 cell phone, or in a bad area. You're --

4 MS. LOCKARD: Let me put you on speaker and see if
5 that's any better.

6 THE COURT: A hundred times better.

7 MS. LOCKARD: But -- okay. So we need to be able to
8 reasonably identify the records in order to request them. So
9 we need periods of treatment. We don't need --

10 THE COURT: Right.

11 MS. LOCKARD: -- specific -- every time someone went
12 to the doctor.

13 THE COURT: Right.

14 MS. LOCKARD: You know. So --

15 THE COURT: Right. My -- the answer to my question,
16 Mr. Slater, would be, with regard to (g), if the answer is yes
17 to a particular condition, you have to identify the provider
18 that treated or diagnosed the condition.

19 Like counsel said, the range of dates that they have
20 to request records, all it asks for is approximate date of
21 onset, treatment received, and outcome, is relatively simple.
22 So if a particular plaintiff visited a doctor, I don't know,
23 for high blood pressure, whatever, 15 times, I wouldn't
24 envision that you would have to list 15 separate dates.

25 I would envision plaintiff would say something like,

1 from 2015 to the present who the doctor is, I take X drugs,
2 and then it's not particularly burdensome. So with that in
3 mind, let me just go down this list and clarify for the
4 Court's benefit exactly what language is proposed, okay?

5 Because there's underlines, and there's cross-outs.
6 Persistent constipation, is that the proposal?

7 MS. LOCKARD: That is defendant's proposal. We
8 added persistent.

9 THE COURT: Okay.

10 MS. LOCKARD: And the plaintiffs want none of it.

11 THE COURT: It stays in. Diagnosed and treated
12 depression/anxiety. Is that what defendants want?

13 MS. LOCKARD: Right. Diagnosed and treated
14 depression/anxiety. And the literature --

15 THE COURT: Counsel --

16 MS. LOCKARD: -- indicates --

17 THE COURT: -- okay, counsel, I just want to know
18 what the description is.

19 MS. LOCKARD: Okay.

20 THE COURT: It stays in.

21 MS. LOCKARD: Sure.

22 THE COURT: Persistent diarrhea.

23 MR. SLATER: Your Honor, can we go back to
24 emotional injury? Because those same questions are asked on
25 page 16, where we ask provide the providers as well and it's

1 discusses emotional injury. It says, are you claiming a
2 diagnosed mental and emotional injury? So it seems to be
3 completely duplicative. So I have a problem with this one.
4 We don't mind giving the information, but it's already asked
5 for previously in the PFS.

6 THE COURT: Now this -- doesn't page 16 ask if they
7 allege this type of injury from the use of the drugs, and the
8 question that we're dealing with now, doesn't it go generally
9 to plaintiff's medical history, whether or not they're saying
10 it was caused by the drugs?

11 MS. LOCKARD: Correct.

12 THE COURT: So it stays in. Persistent diarrhea, is
13 that the language?

14 MS. LOCKARD: Correct.

15 THE COURT: Stays in. Diverticulitis, is that the
16 language?

17 MS. LOCKARD: Yes.

18 THE COURT: Stays in. Hypertension, high blood
19 pressure, is that the language?

20 MS. LOCKARD: Yes.

21 THE COURT: Stays in. Hypotension, low blood
22 pressure, is that the proposal?

23 MS. LOCKARD: Yes.

24 THE COURT: Stays in. What is an intestinal
25 obstruction?

1 MS. LOCKARD: It is a frequent symptom of abdominal
2 cancer. It can be a mis-diagnosis, or the -- the obstruction
3 itself can be the cancer.

4 THE COURT: Well how does a plaintiff know what this
5 is?

6 MS. LOCKARD: I believe if a person has been
7 diagnosed with an intestinal obstruction it's a pretty serious
8 diagnosis and usually they would know. There's a high
9 prevalence of intestinal obstruction in patients with
10 abdominal cancer, the physical colon cancer.

11 THE COURT: Is that a diagnosis that a doctor would
12 give?

13 MS. LOCKARD: Yes, it is.

14 THE COURT: All right. Stays in. Malabsorption?

15 MS. LOCKARD: That's the language --

16 THE COURT: Stays in.

17 MS. LOCKARD: -- maybe -- okay.

18 THE COURT: Persistent nausea.

19 MS. LOCKARD: Correct.

20 THE COURT: Stays in. Can we change obesity to
21 diagnosed obesity?

22 MS. LOCKARD: Yes, we can change that.

23 THE COURT: Okay. Put -- add diagnosed obesity,
24 because someone may have a different definition of what
25 obesity is.

1 Pulmonary embolism, blood clot in lung, is that what
2 you want?

3 MS. LOCKARD: Yes.

4 THE COURT: Stays in. Refractory, celiac disease,
5 is that what you want?

6 MS. LOCKARD: Right, refractory celiac disease.

7 THE COURT: Stays in. Small intestinal bacterial
8 overgrowth. What the heck is that?

9 MS. LOCKARD: It is associated with gastro
10 intestinal or gastric cancers.

11 THE COURT: Is that a diagnosis, or is that
12 something --

13 MS. LOCKARD: That's part of an obstruction.

14 UNIDENTIFIED COUNSEL: It's an obstruction of the
15 intestine, Your Honor.

16 THE COURT: Counsel, how would a plaintiff know
17 that?

18 MS. LOCKARD: Well if they don't know it, then they
19 will probably not answer it. But if they do know it, then I
20 think we're entitled to ask. There is a recent article that
21 has published results of studies of gastric cancers in certain
22 populations, and have found that up to 30 percent of GI cancer
23 patients, nurses, and 16 percent of the general population
24 test positive for an intestinal bacterial overgrowth.

25 You know what, it may seem like a foreign concept to

1 those who haven't experienced this, I think if you have
2 experienced this and been treated for it, you'd probably know
3 it.

4 THE COURT: How about we take that out, and if it's
5 present, it's going to be in the medical records. So that's
6 out.

7 Stroke of any type, hemorrhage, whatever that word
8 is, et cetera, is that what you want?

9 MS. LOCKARD: Right.

10 THE COURT: It says in.

11 MS. LOCKARD: That word's ischemic.

12 THE COURT: It stays in.

13 MR. SLATER: Can I ask a question? I don't mean to
14 interrupt, Your Honor. But I have no concept of how somebody
15 having had a stroke or a TIA, how that's somehow is a --
16 connected to a intestinal cancer.

17 MS. LOCKARD: Well there's a 2012 article in the
18 American Heart Association Journal Stroke, which indicates
19 that cancers, diagnosed or undiagnosed, increase the risk of
20 stroke. And patients that have stroke are more likely to be
21 subsequently diagnosed with a cancer.

22 MR. SLATER: What cancers? Intestinal cancers,
23 colon cancers?

24 THE COURT: Counsel, I accept your representation
25 made at the beginning of this conversation. Stoke stays in,

1 TIA stays in. What does an unexpected weight loss -- it's
2 another -- it's a very vague term. What -- can you be more
3 specific?

4 MS. LOCKARD: It is -- it is a non-specific term,
5 but it is a marker or indication of undiagnosed or latent
6 cancer. It's a frequent -- one of the very first frequent
7 first signs or symptoms a patient can have of a variety of
8 cancer, including gastric, colon, kidney, liver.

9 It's an unexpected or sudden weight loss. I mean,
10 we could say sudden weight loss, I suppose. And, again, this
11 is something that's been diagnosed or treated, they've gone to
12 a doctor for it.

13 THE COURT: Can you say sudden substantial weight
14 loss?

15 MS. LOCKARD: If that's Your Honor's ruling.

16 THE COURT: Yes.

17 MS. LOCKARD: We can add that.

18 THE COURT: And persistent vomiting stays in. Okay?

19 MR. SLATER: There's one issue that I think was not
20 red lined, but I think we have to just discuss it. On page 23
21 about six or seven lines from the bottom it says, infectious
22 disease, such as typhoid fever, encephalitis, H pylori. We
23 have no problem with that, other than we don't want it be such
24 as, because that's too vague. If they want to limit it to
25 those three infectious diseases, that's fine. But the such as

1 could be very problematic.

2 THE COURT: Counsel?

3 MS. LOCKARD: So you want us to take out the such
4 as, and just list those three? I think that's fine.

5 THE COURT: Okay.

6 MS. LOCKARD: Because we're not looking to add
7 anything, so I can erase that.

8 THE COURT: Good. Okay. Great. So let's -- I
9 still have defendants' letter. It's just easier to go through
10 that order. The process for dismissal of peripheral
11 defendants. I'm delighted that you're coming along with that.
12 And we would be very pleased if we can get that order by the
13 September 25th conference.

14 The issues regarding the ANDA production, at least
15 what's in the paperwork, defendants' paperwork seems very
16 reasonable. You worked out the issue with the one party. The
17 one ANDA that wasn't in the ECTD format, it makes sense not to
18 require them to convert it to that format.

19 Are there any other issues regarding the ANDAs,
20 plaintiff?

21 MR. SLATER: Not that we're aware of at present.

22 THE COURT: Terrific. It looks like the JPML
23 petition will be heard now in December. Is that right?

24 UNIDENTIFIED COUNSEL: That's correct. It's
25 pending.

1 THE COURT: Okay. And will there be substantial
2 objection from the defendants? Is it the "lead defendants"
3 who are going to be objecting?

4 MR. GOLDBERG: Your Honor, certainly some defendants
5 plan to object. The -- you know, and some of them are in the
6 API Finish Dose Manufacturing Group, and some are at other
7 levels.

8 THE COURT: Okay.

9 MR. GOLDBERG: So -- and that -- that objection will
10 be filed -- or those objections need to be filed at the latest
11 September 19th.

12 THE COURT: Okay. Let's take a hypothetical. If
13 the request is denied, there's no issue. If the request is
14 granted, will it necessitate that these plaintiffs go back and
15 answer this fact sheet again, or we'll be dealing with an
16 entirely new set of plaintiffs?

17 MR. SLATER: I think it would be new plaintiffs,
18 Your Honor, except to the extent that a plaintiff may have
19 taken both medications, which I think that would be an easy
20 fix on this fact sheet. For example, if someone took, you
21 know, Losartan and Valsartan, it can be addressed. We'll just
22 have to format the document once it's accepted, if it's
23 accepted.

24 THE COURT: Well what about the issue of when we
25 have our big meeting in December, and we decide all the ESI

1 and document request issues, if we don't have an answer yet on
2 the amendment, and if it's denied, like I said, we don't have
3 a problem, we know the case is just limited to Valsartan, but
4 if we find out -- I don't know how long it takes to decide
5 these things, say in January that other sartans are involved
6 in this case, will it involve duplicate work on the
7 defendants' part to search for responsive ESI and documents?

8 MR. SLATER: I would not agree so because we're
9 going to try to fashion the search terms to cover sartans in
10 general, because it would be relevant regardless of whether it
11 resulted in if there was contamination in another sartan from
12 the manufacturing facilities, we would think that would be
13 relevant regardless of whether Losartan and Irbesartan or the
14 other sartans get folded in or not.

15 So I think our search terms are probably going to
16 encompass the language or -- or encompass terms that take that
17 in anyway. Unless, you know, something that comes up new that
18 shows that that contamination happened in a different way.
19 And we haven't seen anything like that yet.

20 THE COURT: Yeah.

21 MR. SLATER: And that's -- I'm just talking in a bit
22 of a vacuum, but that's -- that's our expectation I think.
23 And certainly anybody can correct me if I'm wrong.

24 THE COURT: If the defendants don't object to that
25 scope of discovery, we don't have a problem. But I'm going to

1 guess we might have a problem. Defendants, what do you say?

2 MR. GOLDBERG: Well, Your Honor, I mean, I think
3 this is one of the -- one of the reasons that there is going
4 to be an opposition to their petition to expand. The way the
5 petition is drafted it would include not just Irbesartan and
6 Losartan but five other ARB drugs. It would include not just
7 the -- the three contaminants or impurities that have been
8 identified by the FDA, it would include any and all
9 contaminants or impurities that are carcinogenic, none of
10 which have been identified by the plaintiffs, and none of
11 which have been identified by the FDA.

12 It's a complete uncertainty as to what -- what
13 contaminants or impurities will be at issue, and what injuries
14 would be at issue, and what processes for manufacturing would
15 be at issue. And so, not surprisingly, defendants are
16 opposing, because there's really no basis to expand the matter
17 in the way that's been proposed.

18 THE COURT: Why --

19 MR. GOLDBERG: And we do think it's going to be very
20 complicated. And let me just say, I mean, one other point to
21 note, Your Honor, is that there are more than 50 manufacturers
22 of those other ARBs. And as, you know, Valsartan has
23 demonstrated, getting the case organized simply from a service
24 standpoint, jurisdictional standpoint, et cetera, will become
25 another -- another complexity that the Court's going to have

1 to deal with.

2 And of course we'd want there to be efficiency, but
3 there's no precedent in the JPML case law to suggest that you
4 could have an MDL where no actual claims as to any issues or
5 injuries.

6 THE COURT: I guess I have a question. Why would
7 plaintiff propose, if it's true, and I don't know if it's
8 true, to expand the case as to products that haven't been
9 recalled, or there's no information that they're contaminated?
10 I thought we were just talking about the other sartans. Why,
11 if Mr. Goldberg is correct, are plaintiffs trying to expand
12 the litigation beyond the products that have either been
13 recalled, or voluntarily recalled, or which have been
14 identified as having contamination?

15 MR. SLATER: He's incorrect. But we're obviously --
16 we're not going to be bringing in medications that there's no
17 reason to believe there's been contamination with a
18 carcinogen. At this point we know Irbesartan and Losartan,
19 and that would be the focus. All we wanted to make sure of is
20 that we didn't have to keep going back to the extent that a
21 sartan is found to be contaminated. So, you know, it very
22 well may be that the JPML says, okay, well we'll include
23 Losartan and Irbesartan, and if another sartan turns out to be
24 contaminated, come ring our doorbell again. That's the
25 intent.

1 THE COURT: Okay.

2 MR. SLATER: I'm not really sure what Mr. Goldberg's
3 referring to.

4 THE COURT: All right. Well it's good that we're
5 having this discourse, because it sounds like the defendants
6 can go down a rabbit hole that plaintiffs aren't going, so
7 maybe you ought to just talk about what the intent is, and
8 this way defendants can address only what's genuinely at issue
9 in the case.

10 Okay. Number five on defendants' letter is
11 defendants' fact sheet. Are the parties on track to present
12 that, or at least address it at the next in-person conference
13 on September 25?

14 MR. SLATER: It doesn't look that way at all. As
15 Your Honor has seen, we sent that to the defense in June. And
16 the following up part has been -- there hasn't been a sense of
17 urgency, because we've been working out the plaintiff's fact
18 sheet, and dealing with these other issues, but we've never
19 gotten a response since June.

20 And from what we're reading here, they're
21 reorganizing the defendant fact sheet, and going to send us,
22 it sounds like reformulated documents.

23 So we don't even know what we're going to get back
24 after, you know, three months after sending them -- two and
25 half, three months after sending them our draft.

1 MR. GOLDBERG: Your Honor, you may recall that we
2 discussed this all hearings. They sent us a draft of the fact
3 sheet that had, but didn't delineate between the defendants
4 and the supply chain. And we agreed to exchange, at your
5 suggestion, the -- the fact sheet should be so delineated, we
6 were revising it at -- you know, and we intend to send them a
7 draft back this week or next.

8 It's not -- there -- they have now served all of
9 their document requests, the information and the fact sheet is
10 certainly encompassed in those requests. We see no reason it
11 shouldn't be able to be resolved by the September 25th
12 conference, or at least discussed with the Court then.

13 THE COURT: Give me a date when you're going to get
14 the comments served, Mr. Goldberg. Defendants' comments on
15 plaintiff's draft of the defendant fact sheet.

16 MR. GOLDBERG: We'll get it to them Monday the
17 sixteenth.

18 THE COURT: Terrific. Okay. Let's see if we can
19 tee up, hopefully, all issues, but at least some issues for
20 September 25th. Okay?

21 Going back a second, now that the -- the PI or
22 personal injury fact sheets are going to be completed, where
23 do the parties stand on the fact sheets for the named class
24 reps?

25 MR. SLATER: We -- and, Your Honor, we had been

1 talking with the defense in conjunction with the personal
2 injury GFS, and we're told that they were reformulating what
3 they had previously served based on Your Honor's rulings and
4 what's occurred to date.

5 And we've asked the defense when they expect to get
6 us what they propose for those other categories --

7 (Mechanical interference)

8 MR. SLATER: I'm sorry. So there -- we've asked
9 them for their reformulated fact sheets. In fact, we hope to
10 get today, and asked who on their side's going to be handling
11 the negotiation of those, because we want to get that started,
12 if we can. They told us who would be initially negotiating
13 for them.

14 And. you know. our hope is. and our expectation is
15 that all of the fact sheets should ultimately be finalized at
16 the same time so we can implement them all at the same time
17 with a single order.

18 That's our expectation.

19 THE COURT: Mr. Goldberg, when do you think the
20 defendants can get to plaintiffs the proposed fact sheets for
21 the named class reps?

22 MR. GOLDBERG: Your Honor, I -- I have to -- I have
23 not been involved in this discussion. I don't know if any of
24 my colleagues were part of those communications with
25 plaintiffs.

Colloquy

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1 MR. SLATER: That was Victoria Lockard -- that's Ms.
2 Lockard who --

3 MR. GOLDBERG: Okay.

4 MR. GOLDBERG: -- because she apparently, maybe got
5 disconnected.

6 OPERATOR: Is now in the conference.

7 MR. GOLDBERG: And come back.

8 MR. SLATER: Victoria?

9 (Pause)

10 MS. LOCKARD: Okay. I'm un-muted. I apologize. I
11 hit the -- I hit the wrong button when I went to un-mute the
12 first time.

13 THE COURT: The question we had, Ms. Lockard, is we
14 -- if you were -- I'm not sure you were on the line or may
15 have been cut off, but the defendants --

16 MS. LOCKARD: About the fact sheet.

17 THE COURT: -- the defendants' comments on
18 plaintiff's draft of the fact sheets to defendants will be
19 served by September 16. And then I had asked, now that it
20 looks like we finalized the plaintiff's fact sheets for the
21 personal injury cases, what was the status of the fact sheets
22 for the named class reps? And can we have a deadline for
23 defendant to get their proposal to the plaintiff?

24 MS. LOCKARD: So I think now that we've reached
25 agreement on the primary fact sheet, I think it -- it should

1 be not much trouble to get the -- the fact sheet for the
2 economic class reps, and medical monitoring class reps.

3 I think the third-party payor sheet is going to be
4 much different, and that will need more time. But I think we
5 can get the other back, you know, to them within a week. And
6 then we can try to get these three entered together. But I
7 don't think we want to wait for the third-party payor fact
8 sheet because that is going to be different and require some
9 additional, and probably substantial negotiation.

10 MR. SLATER: I'm not -- I think it's not going to be
11 -- I don't think it's going to be as big deal as counsel was
12 concerned. On the plaintiff's side, we've been working very
13 hard to figure out based on what was initially sent to us a
14 long time ago, what would be reasonable.

15 And we've been sitting by, we have people ready to
16 negotiate and talk to the defense. I -- I don't think it's
17 going to be as big a deal. I mean, the PPG plaintiffs are
18 ready to produce what they need to produce to protect those
19 claims, and a lot of it is just data.

20 So we're ready to negotiate, that's why we asked
21 who's going to be ready to talk. I mean, we're ready to talk
22 next week, we're ready to start negotiating those as soon as
23 the defense is ready.

24 MS. LOCKARD: Well, and we did agree to have a meet
25 and confer next week. But we need -- I've not gotten a draft

1 from you all back from the initial draft we sent around. But
2 if we can get that in time for the meet and confer, then we
3 can probably make some progress.

4 UNIDENTIFIED COUNSEL: The reason we didn't send it
5 is because we were told by the defense that you were
6 reformulating and going to re-serve the fact sheets on us.

7 THE COURT: Why don't you do that. Can you do that
8 by say the -- when are you meeting?

9 MR. SLATER: There's nothing's scheduled. We're --
10 we're ready to put -- we would like to start talking next
11 week, as soon as possible.

12 THE COURT: Okay. Let's do it by the eighteenth,
13 which is next Wednesday. Defendant will send proposed fact
14 sheets for the named class reps. Right? Do your best, Ms.
15 Lockard, let's get that ball rolling. And hopefully you'll
16 talk about it before the twenty-fifth. Okay?

17 MS. LOCKARD: Yes. We definitely will. We're --
18 we're eager to get those entered. So --

19 THE COURT: Okay. So I'll put that down -- I'll put
20 this in an order -- confirm all this in an order. September
21 18th for the other named -- for the named class rep plaintiff.
22 Okay?

23 And then let me just see, service of process update
24 we've talked about. There's not much more to add. And the
25 last issue, the addition of Mylan N.V. Here's my feeling

1 about that, counsel, after reading the papers. It seems to me
2 that if plaintiffs are able to plead a plausible claim against
3 Mylan N.V., we should amend the short form complaint.

4 But if they can't plead a plausible claim at this
5 point, it shouldn't be amended. So I view it as akin to a
6 motion for leave to file an amended complaint. And I -- my
7 only question is whether we can do that on -- whether we
8 should do that on letter briefs, or a motion. I just need
9 plaintiffs to provide plausible averments why Mylan N.V.
10 should be included, and not just they're a parent or they're
11 at the top of the food chain and that's enough. That's not
12 going to do it.

13 What say you, plaintiff?

14 MR. SLATER: I'm not in a position to get into the
15 substance of it at this point, Your Honor. But if -- if you
16 want us to make a submission before the next conference, we
17 certainly can do that. And then another option could be, if
18 the defense doesn't want them added, and I think I understand
19 why at this point, perhaps an order could be entered tolling
20 any statute of limitation against that entity while we conduct
21 discovery, and actually learn about Mylan and its relationship
22 with the other entities.

23 And then -- and then we can go from there. And, in
24 fact, I -- I will note that it is in the master complaint.
25 They are -- they are a defendant in the master complaint.

Colloquy

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1 So --

2 THE COURT: Oh. Okay.

3 MR. SLATER: -- I was just on that, so that moots
4 what if just said. They're already in the case.

5 THE COURT: All right.

6 MR. SLATER: We just have to add them onto the short
7 form.

8 THE COURT: All right. So if they're already in the
9 case, Mylan counsel, is there a good reason not to include
10 them on the short form complaint?

11 MR. REEFER: Well, hi, Judge. This is Jason Reefer
12 again sitting in for Clem Trischler today. You know, I think
13 our submissions sort of plots out, you know, what went into
14 the short form complaint, and the reason why we don't believe
15 Mylan N.V. is properly included.

16 Part of our objection, frankly, Your Honor, was we
17 didn't want to be -- we didn't want acquiescence to be viewed
18 as --

19 (Mechanical voice interruption)

20 MR. REEFER: -- I'm sorry. We didn't want
21 acquiescence to be viewed as agreeing that Mylan N.V. is a
22 proper party.

23 THE COURT: Got it.

24 MR. REEFER: Because our position is simply that,
25 you, know Mylan N.V. played no role in the manufacturing, or

1 distribution, and sale of this product. And as Your Honor has
2 noted, you know, a parent corporate -- a parent relationship
3 with a subsidiary is not sufficient to impose liability.

4 And the fact remains, Judge, if -- and the fact
5 remains that plaintiffs have been writing Mylan N.V. to the
6 short form complaints in a section that allows for the
7 addition of a party that aren't expressly listed in the check
8 boxes. So, I mean, I don't really view that there is any need
9 to amend the short form complaint. You know, I think more
10 than anything, we just want to make a record that we -- we
11 don't see any basis for the amendment.

12 THE COURT: As far as the Court is concerned, it has
13 absolutely no problem in the order it's going to enter
14 indicating that Mylan N.V., or any Mylan entity objects to the
15 inclusion of Mylan N.V. as a party. We've said it time, and
16 time, and time, and time again, everybody's defenses are
17 preserved.

18 Judge Kugler is going to set the date when the
19 appropriate motions to be dismissed are going to be filed and
20 decided. So there's no problem with that reservation. Mr.
21 Slater, in terms of efficiency, is it -- I mean, do you want
22 to amend it? Or can people just continue to include the name
23 in the other category, write it in?

24 MR. SLATER: It makes more sense to just add them to
25 the document, so that it's -- it's part of the document.

1 THE COURT: All right. The Court's going to rule
2 that the short form complaint is amended. It will make it
3 clear in the order that all defenses are preserved, nothing is
4 waived. Could you send the Court a revised form, Mr. Slater,
5 and the Court will enter it?

6 MR. SLATER: Thank you, Your Honor. You'll have
7 that by tomorrow at the latest.

8 THE COURT: Okay. I think that exhausts all the
9 issues in the letters and the agenda, but we're together, are
10 there any other issues or matters that we need to address
11 while we're all here?

12 MR. GOLDBERG: Your Honor, this is Seth Goldberg. I
13 will send an email communication to plaintiff's executive
14 committee. But we have in here, we have to produce some
15 things on Tuesday the ECTD documents and some of the other
16 information.

17 Plaintiffs, when we were recently sending a, you
18 know, one set of the ECTD documents. and I guess to Mr.
19 Slater's attention, as opposed to sending multiple copies of
20 the same production.

21 And they presented that, and then we would -- each
22 of the defendants would send a cover letter with the other
23 information as well.

24 MR. SLATER: I just -- I would want to follow the
25 protocol we have in place now. Because the most important

1 thing is that these productions go to our vendor that handles
2 our document repository system so that they can load it.

3 MR. GOLDBERG: And I don't think this is being --
4 these productions are not -- these are purposefully outside of
5 the ESI protocol.

6 MR. SLATER: No, but they should go to our vendor.
7 They're still getting loaded -- they're still going to have to
8 load there and make it available to us on our system. I mean,
9 you can send it to me if you want, but, I mean, we have people
10 that are handling making that accessible to us on -- on a
11 system that we can share.

12 Unless I'm wrong about that. I don't think I am,
13 though.

14 MR. GOLDBERG: Okay. Well we'll look into that and
15 if -- if that's not something that we can do because this is
16 outside of the protocol we'll send it to you, and then, you
17 know, you can have it distributed among your colleagues as you
18 feel --

19 MR. SLATER: I don't want to take up the Court's
20 time. I'd much rather you -- you communicate with us. If you
21 -- I don't understand why you wouldn't send it to our vendor
22 as everything else is being sent to them. They're the ones
23 who are putting things up on our system. Whether -- I don't
24 know why you're saying outside the protocol. I mean there was
25 modification made on the format of production. But the fact

1 that they need to be produced and be put on our system doesn't
2 changed, so I'd rather not create a step where I have to then
3 send this stuff to somebody else, when you can just send it
4 directly. We lose days on that.

5 So we can talk about it off line, there's no reason
6 to waste the Court's time with this.

7 THE COURT: Anything else, counsel?

8 MR. STANOCH: Your Honor, this is David Stanoch at
9 Golomb Honik. I ask -- i have a true housekeeping question
10 for Your Honor. We're coming up on the deadline for
11 plaintiff's side first quarterly time and expense report to
12 the Court.

13 THE COURT: Yes.

14 MR. STANOCH: And I want to get Your Honor's input
15 on just the logistics of service. We were contemplating
16 perhaps a letter to Your Honor and Judge Kugler, and in the
17 letter having imbedded links that you can use to access the
18 summary and detail report required by the TMO-4. But if Your
19 Honor prefers something else, or Judge Kugler prefers
20 something else, of course we will accommodate.

21 THE COURT: Can I ask, these reports you're
22 referring to, they're prepared by, what, an accountant?

23 MR. STANOCH: They're going to be prepared by the PC
24 in conjunction with the CPA, yes, Your Honor.

25 THE COURT: Are they extensive? How big are they?

1 MR. STANOCH: Yes. Especially the detail report,
2 Your Honor.

3 THE COURT: Can you give me just an idea of how many
4 pages we're talking about?

5 MR. STANOCH: The detail report is -- is scores of
6 pages, and -- and the summary report is shorter. Maybe a
7 dozen or so. We can send a PDF of the -- of the summary
8 report, and in the letter have a link to the detail report,
9 because that's where you're going to have, you know, hundreds
10 of pages of volume potentially.

11 THE COURT: Okay. I'll tell you what, since this is
12 the first time doing it, why don't you send us the summary
13 report hard copy. That will be only a few pages. And a link
14 to the document that you say is hundreds of pages. And if
15 that creates some sort of problem on our end, we'll let you
16 know. But since this is the first report --

17 MR. STANOCH: Okay. Very good, Your Honor.

18 THE COURT: -- I have a question about that. I
19 don't know, is -- do you anticipate that the defendants are
20 going to see a copy of this report?

21 MR. STANOCH: No, Your Honor. The CMO report are
22 not provided for that.

23 THE COURT: And but they'll get a copy of the
24 enclosure letter, right?

25 MR. STANOCH: Yeah. We could do that, but then with

1 the proviso that, you know, the link we would be embedding in
2 the letter for the detail would then be available and
3 accessible, so I can send a different letter to present
4 liaison counsel, letting them know that we've made the
5 transmission to the Court.

6 THE COURT: Yes. What I just want to be sure of is
7 that the -- I understand it's work product. The defendant
8 can't see the nuts and bolts of the numbers that you're going
9 to provide the Court. Of course I understand that. That's
10 work product. But I do want the defendants to know when and
11 what you're sending to the Court.

12 MR. STANOCH: Absolutely. We'll -- we'll figure it
13 out, Your Honor, and make it look right so that they know
14 what's being sent, but they're not going to receive a copy of
15 anything that would not be entitled to get.

16 We'll figure that out, Your Honor.

17 THE COURT: All right. Let me just add one point
18 that I forgot to mention. You will get an order and opinion
19 on the issue of the discovery of plaintiff's litigation
20 funding early next week, in time to take it into account when
21 you finalize the plaintiff's fact sheet.

22 Since that fact sheet is going to be presented to
23 the Court on or about September 25th at the conference, you'll
24 have the direct -- the Court's directions with regard to
25 litigation funding before then.

1 Anything else? Counsel, thank you very much for
2 your time. And I thank you again for your indulgence. We
3 switched this from yesterday to today. If any issues come up
4 that needs immediate attention before the twenty-fifth
5 in-person meeting, let us know. Otherwise, we'll see you
6 then. Have a good day. We're adjourned.

7 (Proceedings concluded at 5:03 p.m.)

8 * * * * *

9 C E R T I F I C A T I O N

10 I, Josette Jones, court approved transcriber, certify that the
11 foregoing is a correct transcript from the official digital
12 audio recording of the proceedings in the above-entitled
13 matter.

14
15 _____

16 JOSETTE JONES

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